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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/774,613	02/10/2004	Tomoko Takeshita	HIRA.0141	1668
7590	02/04/2005		EXAMINER	
Stanley P. Fisher Reed Smith LLP Suite 1400 3110 Fairview Park Drive Falls Church, VA 22042-4503			GALVEZ, JAMES JASON	
			ART UNIT	PAPER NUMBER
			1647	
			DATE MAILED: 02/04/2005	

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/774,613	TAKESHITA ET AL.	
	Examiner	Art Unit	
	J. Jason Galvez	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 02 December 2004.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-6 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-6 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 10 February 2004 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>5/04</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group 1 and species B (G_α11) and C

- 5 (G_α14) in the reply filed on 12/02/2004 is acknowledged. Claims 7-12 have been withdrawn from consideration without prejudice. Accordingly, claims 1-6 and species B and C are under examination.

Oath/Declaration

- 10 A new oath or declaration is required because the oath/declaration is written in Japanese and does not appear to coincide with the instant application. The new oath or declaration must properly identify the application of which it is to form a part, preferably by application number and filing date in the body of the oath or declaration. See MPEP § 602.

15

Priority

- Acknowledgment is made to Applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in Application No. 10/774,613, filed on 2/10/2004. However, a translation of the foreign priority document has not been supplied. If Applicant is to rely on the foreign priority document to overcome prior art or some other rejection a translation of the document must be supplied.

Drawing Objections

The drawings are objected to because Fig. 7 contains the typographic error:

"GENE TRANSFICTION". Corrected drawing sheets in compliance with 37 CFR

1.121(d) are required in reply to the Office action to avoid abandonment of the

- 5 application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must
- 10 be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the
- 15 examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

Claims 2 and 6 are objected to because of the following informalities: they recite

- 20 G₁₁ and G₁₄ where these molecules were previously recite as G_{11α} and G_{14α}, respectively. Claim language should be consistent when referring to identical matter.

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Claim 5 contains a typographic error: "subunitconstituted". Appropriate correction is required.

Claim Rejections - 35 USC § 112

- 5 The following is a quotation of the first paragraph of 35 U.S.C. 112:
- The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
- 10 Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for recombinant cells and methods of producing recombinant cells comprising known GPCRs and a chimeric G α subunit comprising specified regions of G₁₁ α and G₁₄ α , does not reasonably provide enablement for
- 15 recombinant cells and methods of producing recombinant cells comprising GPCRs, as broadly claimed, and a chimeric G α subunit comprising G₁₁ α and G₁₄ α wherein the G α subunit is constituted by a "portion of" G₁₁ α and G₁₄ α . The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.
- 20 The factors to be considered when determining if the disclosure satisfies the enablement requirement have been summarized as the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breath of
- 25 claims. *Ex Parte Forman*, (230 USPQ 546 (Bd. Pat. App. & Int. 1986)); *In re Wands*, 858 F.2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988).

Claims 1-6 are drawn to recombinant cells and methods of producing said recombinant cells consisting of GPCRs generically. The claims encompass orphan GPCRs. Orphan GPCRs are "not activated by any known transmitters and thus are genes with unknown function" (Lin et al., Ann Med. 2004, Vol. 36(3): pp. 204-214, esp.

- 5 p. 204: column 2, paragraph 2). Therefore a person of ordinary skill in the art would not know how to make and/or use the invention as claimed. Furthermore, the invention as claimed merely acts as an invitation for experimentation by means of further characterizing receptors with unknown properties.

Claims 1-6 are drawn to recombinant cells and methods of producing said recombinant cells consisting of chimeric G_α subunits made up of a "portion of" G_{11α} and G_{14α}. Applicant is claiming cells and methods that contain chimeric proteins made up of portions of two different proteins. As claimed a portion could constitute portions within the recited proteins and portions that contain additional amino acids to those that are within the recited proteins. What portions will constitute a functional protein? It is possible that certain portions of the two proteins when combined will result in a protein that is devoid of any function. It is well known in the art that protein function is extremely sensitive to changes in primary structure. For example, Luck et al. have reported that even single amino acid changes can measurably alter polypeptide activity (Molecular Endocrinology 1991, Vol. 5(12): pp. 1880-1886, esp. p. 1881, table 1).

20 Therefore, it would not be possible to predict what portions of G_{11α} and G_{14α} would make a functional chimeric G_α subunit.

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For the reasons set forth, without further guidance a person of ordinary skill in the art would not be able to practice the invention as claimed without undue experimentation.

Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply

- 5 with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The factors to be considered when determining if the disclosure satisfies written

- 10 description requirements include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, and any combination thereof.

Claims 1-6 are drawn to recombinant cells and methods of producing said recombinant cells consisting of GPCRs generically. The claims currently encompass a 15 genus of receptors that are divergent in function. To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing characteristics of the genus. Since Applicant has provided no required structures, properties, or functions, the skilled artisan cannot envision the claimed genus of receptors.

- 20 Claims 1-6 are drawn to recombinant cells and methods of producing said recombinant cells consisting of chimeric G_α subunits made up of a "portion of" G_{11α} and G_{14α}. The disclosure does not limit what constitutes a "portion of" G_{11α} and G_{14α}.

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Therefore the claim is interpreted to mean any "portion of" G_{11α} and G_{14α}, including portions that may include additional amino acid sequences not found in either protein.

As interpreted, the chimeric protein recited encompasses a genus of proteins without any limitations other than having a "portion of" G_{11α} and G_{14α}. Furthermore, Applicant

5 has not described structural and/or functional characteristics of the claimed "portion of" G_{11α} and G_{14α}. To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing characteristics of the genus. Since Applicant has provided no required structures, properties, or functions, the skilled artisan cannot envision the claimed genus of proteins.

10 Claims 2 and 6 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Applicant recites chimeric proteins constructed from "the N-terminal side" and "the C-terminal side" of specified proteins. However, it is unclear as to what would make up an "N-terminal side" and a "C-terminal side". For 15 instance, how many amino acids from the N-terminal region make up an "N-terminal side"?

Claims 5-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Applicant claims a "group of ...cells". The recitation 20 of group makes the claim indefinite. What constitutes a group, as claimed?

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- 5 (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2 and 5-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Nakamura et al. (J Biochem 1996, Vol. 120(5): pp. 996-1001). Nakamura et al. teach recombinant cells and a method of making recombinant cells comprising a GPCR and a chimeric G α subunit comprising segments of G $_{11}\alpha$ and G $_{14}\alpha$ (p. 997: column 1, paragraph 1). Nakamura et al. disclose G α subunits in the following manner: G $_{L2}\alpha$ is G $_{11}\alpha$ and G $_{L1}\alpha$ is G $_{14}\alpha$ (p. 996: column 2, paragraph 1). Thus, Nakamura et al. meet the limitations of the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

20 (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

25 Claims 3-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakamura et al. (J Biochem 1996, Vol. 120(5): pp. 996-1001). Nakamura et al. teach recombinant cells and a method of making recombinant cells comprising a GPCR and a

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chimeric G α subunit comprising segments of G₁₁ α and G₁₄ α (p. 997: column 1, paragraph 1). Nakamura et al. disclose G α subunits in the following manner: G_{L2} α is G₁₁ α and G_{L1} α is G₁₄ α (p. 996: column 2, paragraph 1). Nakamura et al. do not teach the specific timing and ratio of transfected genes. However, it would be obvious to a 5 person of ordinary skill in the art and would, likewise, provide motivation for a person of ordinary skill in the art to conduct routine experimentation in order to optimize conditions for the cotransfection. The following is a relevant quote from MPEP § 2411:

"[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 10 USPQ 233, 235 (CCPA 1955) (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be *prima facie* obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%.); >see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 (The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages.)

Furthermore, the expectation of success is reasonably assured based on the teachings of Nakamura et al. where cotransfections of the instant inventions have been made and due to wealth of knowledge and practice of recombinant DNA technologies.

20

Conclusion

NO CLAIMS ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **J. Jason Galvez, Ph.D.** whose telephone number is

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571-272-2935. The examiner can normally be reached Monday through Friday 9 AM to 5 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Brenda Brumback, Ph.D.** can be reached at **571-272-0887**.

The fax phone number for the organization where this application or proceeding

5 is assigned is **571-273-8300**. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system,
10 contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

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20 JJG
2/7/2005


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PRIMARY EX VCR